Remarks/Arguments

This Amendment is being filed under 37 C.F.R. §1.114 governing Request for Continued Examination (RCE). This Response is being filed in Response to the Office Action, dated July 18, 2003 is respectfully requested in view of the foregoing amendment and following remarks. No new claims have been added. Claim 1 has been amended. Upon entry of the amendment, Claims 1 through 20 will be pending in the application.

Amendment Filed Under 37 C.F.R. §1.114

The amendment has been filed under 37 C.F.R. §1.114 governing Request for Continued Examination (RCE). This paper is appropriate under 37 C.F.R. §1.114 since it meets the reply requirements of 37 C.F.R. §1.111.

Proper Weight Should Be Accorded Preamble

As an initial matter, Applicant respectfully reminds the Examiner that the courts have extensively discussed the proper weight which is to be accorded a preamble, for example:

"In general, a preamble limits the [claimed] invention if it recites essential structure or steps, or if it is 'necessary to give life, meaning, and vitality' to the claim." Catalina Mktg. Int'l, Inc. v. Coolsavings.com, Inc., 289 F.3d 801, 808, 62 USPQ2d 1781, 1784 (Fed. Cir. 2002) (quoting Pitney Bowes, Inc. v. Hewlett-Packard Co., 182 F.3d 1298, 1305, 51 USPQ2d 1161, 1165 (Fed. Cir. 1999)). "[A] claim preamble has the import that the claim as a whole suggests for it. In other words, when the claim drafter chooses to use both the preamble and the body to define the subject matter of the claimed invention, the invention so defined, and not some other, is the one the patent

protects." Bell Communications Research, Inc. v. Vitalink Communications Corp., 55 F.3d 615, 620, 34 USPQ2d 1816, 1820 (Fed. Cir. 1995). When limitations in the body of the claim rely upon and derive antecedent basis from the preamble, then the preamble may act as a necessary component of the claimed invention. See, e.g., Electro Sci. Indus. v. Dynamic Details, Inc., 307 F.3d 1343, 1348, 64 USPQ2d 1781, 1783 (Fed. Cir. 2002); Rapoport v. Dement, 254 F.3d 1053, 1059, 59 USPQ2d 1215, 1219 (Fed. Cir. 2001); Pitney Bowes, 182 F.3d at 1306, 51 USPQ2d at 1166. On the other hand, "[i]f the body of the claim sets out the complete invention," then the language of the preamble may be superfluous. Schumer v. Lab. Computer Sys., Inc., 308 F.3d 1304, 1310, 64 USPQ2d 1832, 1837 (Fed. Cir. 2002); Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc., 246 F.3d 1368, 1373-74, 58 USPQ2d 1508, 1512 (Fed. Cir. 2001).

It is clear that the language addressed by the Examiner in the Office Action is necessary to give "life, meaning and vitality" to the claim. The position of the device as claimed clearly requires it to be at a position below the larynx. This is evident from the fact that the device is a tracheal cannula which is to be inserted through a tracheotomy incision. Simply stated, the positioning and function that a tracheal cannula serves versus that of a tracheal tube is well defined in the art. A tracheal cannula is a device inserted after a tracheotomy via the tracheal incision and, thus, is necessarily present below the larynx. A tracheal tube in contrast is commonly regarded as a device that is inserted via the mouth of the patient, as shown in Figure 1 of Psaros. The different positioning and function of the respective devices requires different designs as to their length and curvature. Psaros draws such a respective distinction in, at least, column 3, lines 24-27.

Amended claim 1 is quite clear in that the device is a tracheal cannula, which is to be inserted through a tracheotomy incision, at a position below the larynx.

Claim Rejections Under 35 U.S.C §102

Claims 1-4 have been rejected under 35 U.S.C. §102 as being anticipated by Psaros. The rejection of claims 1-4 is improper since Psaros fails to disclose, at least, A tracheal cannula for insertion through a tracheotomy incision ...at a position below the larynx the tracheal cannula including a window covered by an air-permeable membrane, wherein the air-permeable membrane has sufficient permeability to allow for patient vocalization.

Psaros clearly requires the membrane 46 to be made of a material intended to be permeable to NO and further requires that membrane "permeability to oxygen and carbon dioxide in any case preferably should be poor". Psaros, column 4, lines 42 and 43. The amount of NO that is to permeate through the Psaros membrane is exceedingly low. Psaros, column 3 lines 31-40. The contemplated amount of NO in Psaros is measured in parts per million and is not to be higher than 150-200 ppm. Psaros column 1, lines 54-56. Psaros is additionally clear about the deleterious effect higher concentrations of NO have on the body. Psaros column 1, lines 40-56. Applicant respectfully directs the Examiner's attention to Szachowicz (United States patent No. 4,573,460) cited by the Examiner as "pertinent". Szachowicz at column 1 line 67 clearly identifies that vocalization would not occur by excluding all but a few parts per million of a patient's respiratory gases due to the sheer volume of gases needed for vocalization. Since Psaros clearly does not disclose all of the claimed elements, a proper rejection under 35 U.S.C. §102 cannot be made.

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Claims 1-4 are Additionally Non-Obvious Under a Proper 35 U.S.C. §103 Analysis

The claimed invention is additionally non-obvious with regard to, at least, Psaros since there is at the minimum no suggestion or motivation present in the teaching or disclosure of Psaros, or in the references cited by the Examiner, to do what the Applicant has done in the claimed invention. For example, at a minimum a device having, at least, an air-permeable membrane wherein the air-permeable membrane has sufficient permeability to allow for patient vocalization, is not taught or suggested. In fact, Psaros can be considered, at a minimum, to teach directly against arriving Applicant's claimed invention or produce a non-functional device due to, at least, the Psaros membrane requirements. Applicant notes that as thoroughly discussed in a recent court holding:

> "...the essential factual evidence on the issue of obviousness is set forth in Graham v. John Deere Co., 383 U.S. 1, 17-18, 148 USPQ 459, 467 (1966) and extensive ensuing precedent. The patent examination process centers on prior art and the analysis thereof. When patentability turns on the question of obviousness, the search for and analysis of the prior art includes evidence relevant to the finding of whether there is a teaching, motivation, or suggestion to select and combine the references relied on as evidence of obviousness. See, e.g., McGinley v. Franklin Sports, Inc., 262 F.3d 1339, 1351-52, 60 USPQ2d 1001, 1008 (Fed. Cir. 2001) ("the central question is whether there is reason to combine [the] references," a question of fact drawing on the Graham factors)." In re Lee, 61 USPQ2d, 1430 (Fed. Cir. 2002)

Such a rigorous examination required by law clearly would find the claimed invention non-obvious based on at least a study of the problem of allowing patient vocalization while having a tracheal cannula with a cuff in place as solved by the Applicant, and the functionality of the claimed invention. Psaros

is directed toward permitting endogenous NO present in the patient's upper respiratory tract, and as such offers no motivation or suggestion to provide an air permeable membrane while allowing a patient to vocalize following a tracheotomy.

Claim Rejections 35 U.S.C. §103

To properly establish a prima facie case of obviousness three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or combine the reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. See MPEP §2143.

No Motivation or Suggestion for Proposed Modification and Combination Improper

In order to properly make a prima facie case of obviousness, a motivation or suggestion to combine or modify the references must be shown. The MPEP at §2143.01 states, "[I]f proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. In re Gordon, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984)"

Rejection of Claims 5-6 Under 35 U.S.C. §103(a) Improper

Claims 5-6 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Psaros. Claims 5-6 depend either directly or indirectly on claim 1, and are patentable for at least the reasons set forth for claim 1. In

addition, the rejection of claims 5-6 under 35 U.S.C. 103(a) is improper for, at least, the reason that there is no motivation or suggestion to modify the teachings of Psaros to arrive at the Applicant's claimed invention, which includes an air-permeable membrane wherein the air-permeable membrane has sufficient permeability to allow for patient vocalization. In fact, Psaros would lead one of ordinary skill in the art away from the claimed invention since Psaros requires the membrane 46 to have a "permeability to oxygen and carbon dioxide in any case preferably should be poor". Psaros, column 4, lines 42 and 43. The amount of NO that is to permeate through the Psaros membrane is disclosed as being exceedingly low. Psaros, column 3 lines 31-40. The contemplated amount of NO in Psaros is measured in parts per million and is not to be higher than 150-200 ppm. Psaros column 1, lines 54-56. Psaros is additionally clear about not having a greater concentration of NO due to its deleterious effect on the body. Psaros column 1, lines 40-56. In addition, Szachowicz (United States patent No. 4,573,460) cited by the Examiner as "pertinent" directly addresses some of the requirements for vocalization in a patient. Szachowicz at column 1 line 67 clearly identifies that vocalization would not occur by excluding all but a few parts per million of a patient's respiratory gases due to the sheer volume of gases needed for vocalization. Since the proper motivation or suggestion is not present to modify the teaching of Psaros, a rejection under 35 U.S.C. §103(a) is improper.

Rejection of Claims 7-12 Under 35 U.S.C. §103(a) Improper

Claims 7-12 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Psaros as applied to claims 1-6 above and further in view of Muir (U.S. Patent No. 4,759,356). The rejection of claims 7-12 under 35 U.S.C. 103(a) is improper for, at least, the reason that there is no motivation

or suggestion to provide an air-permeable membrane wherein the air-permeable membrane has sufficient permeability to allow for patient vocalization. As discussed above, Psaros requires a membrane that would preclude patient vocalization. Since the proper motivation or suggestion is not present in to modify and/or combine the teaching of Psaros with the teaching of Muir, a rejection under 35 U.S.C. §103(a) is improper.

In addition, the asserted combination of the teachings of Psaros in view of the teachings of Muir would create a non-functional device. Muir teaches a valve designed for devices without cuffs. Combining the teaching of such a valve with the teaching of a device with a cuff, as Psaros, would render the patient unable to breath out since the Muir valve closes upon exhalation and the Psaros membrane has, at best, poor permeability to oxygen and carbon dioxide. Muir is clear that the valve as taught is closed at all times except during inhalation (emphasis added). Therefore, the combination of teachings asserted by the Examiner is directed toward allowing a patient to inhale yet offering no route for exhalation of respiratory gases.

Furthermore, a valve included in Psaros, as proposed by the Examiner, would in no way improve speech in the tracheotomized patient. In fact, the patient would be unable to vocalize at all since the Examiner's proposed device would extend through the mouth and pass by the vocal cords.

Rejection of Claims 13-18 and 20 Under 35 U.S.C. §103(a) Improper

Claims 13-18 and 20 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Psaros as applied to claims 1-6 above and further in view of Abel (U.S. Patent No. 5,056,515). The rejection of claims 13-18 and 20 under 35 U.S.C. 103(a) is improper for, at least, the reason that there is no motivation or suggestion to provide an air-permeable membrane wherein the air-permeable membrane has sufficient permeability to allow for patient vocalization.

For example, the membrane 46 described in Psaros is made of a material intended to be permeable only to NO, and Able does not disclose a membrane. Psaros states "permeability to oxygen and carbon dioxide in any case preferably should be poor". Psaros at column 4, lines 42 and 43. As discussed above it is clear that Psaros does not teach or suggest an air permeable membrane that has sufficient permeability to allow for patient vocalization. Since the proper motivation or suggestion is not present in Psaros, a rejection under 35 U.S.C. §103(a) is improper.

Rejection of Claims 19 Under 35 U.S.C. §103(a) Improper

Claims 19 been rejected under 35 U.S.C. §103(a) as being unpatentable over Psaros and Muir as applied to claim 7 above and further in view of Abel (U.S. Patent No. 5,056,515). As discussed above, the combination with regard to, at least, claim 7 is improper. As such, claim 19 is patentable for at least these reasons.

All Claim Limitations Are Not Taught Or Suggested

It is well established that when even one claimed limitation is not found in the combination of prior art, a rejection under 35 U.S.C. §103 is improper. In re Royka, 490 F.2d 981, 180 USPQ 580 (CCPA 1974).

Rejection of Claims 5-6 Under 35 U.S.C. §103(a) Improper

Claims 5-6 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Psaros. The rejection of claims 5-6 under 35 U.S.C. 103(a) is improper for, at least, the reason that the asserted modification would not yield a tracheal cannula with an air-permeable membrane wherein the air-permeable membrane has sufficient permeability to allow for patient vocalization. The membrane 46 in Psaros is made of a material intended to

be permeable only to NO. Psaros clearly states "permeability to oxygen and carbon dioxide in any case preferably should be poor". Psaros at column 4, lines 42 and 43. Since, at least, the claimed limitation of an air permeable membrane that has sufficient permeability to allow for patient vocalization is not present in the asserted modification, a rejection under 35 U.S.C. §103(a) is improper.

Rejection of Claims 7-12 Under 35 U.S.C. §103(a) Improper

Claims 7-12 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Psaros in view of Muir (US 4,759,356). The rejection of claims 7-12 under 35 U.S.C. 103(a) is improper for, at least, the reason that the asserted combination does not contain an air-permeable membrane wherein the air-permeable membrane has sufficient permeability to allow for patient vocalization. Since all the claimed elements are not present a rejection under 35 U.S.C. §103(a) is improper.

Rejection of Claims 13-18 and 20 Under 35 U.S.C. §103(a) Improper

The rejection of claims 13-18 and 20 under 35 U.S.C. 103(a) is improper for, at least, the reason that an air-permeable membrane wherein the air-permeable membrane has sufficient permeability to allow for patient vocalization is not present in the asserted combination. Since the all of the claimed elements are not present in Psaros, a rejection under 35 U.S.C. §103(a) is improper.

The References Teach Away From Each Other

It is a well-established "general rule" that references that teach away cannot serve to create a prima facie case of obviousness. In re Gurley, 27 F3d 551, 553, 31 USPQ 2d 1131, 1132 (Fed Cir. 1994). A "reference will teach away if it suggests that the line of development flowing from the

reference's disclosure is unlikely to be productive of the result sought by the Applicant." Winner v. Wang, 202 F.3d 1340 (Fed Cir. 2000) citing Gurley at 553.

The line of development flowing from the Psaros disclosure is unmistakably clear. Psaros is directed toward the use of endogenous NO for intubated patients. This is clear from, at least, Figure 1 where the input port 16 having the membrane 46 is shown in the orotracheal location. This positioning allows for NO present above the membrane to be carried from the upper respiratory tract (nose, paranasal sinus). The Psaros membrane 46, as discussed above, is required not to be an air-permeable membrane wherein the air-permeable membrane has sufficient permeability to allow for patient vocalization Since it is clear that the line of development flowing from Psaros would not result in the claimed invention, a rejection under 35 U.S.C. §103(a) can not be properly made.

In summary, Applicant has addressed each of the rejections within the present Office Action. It is believed the application now stands in condition for allowance, and prompt favorable action thereon is respectfully solicited.

Respectfully Submitted

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